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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,163	03/12/2004	John W. Holaday	05213-0077 (13663.105206)	8159
20786 7590 04/11/2007 KING & SPALDING LLP 1180 PEACHTREE STREET ATLANTA, GA 30309-3521			EXAMINER YAEN, CHRISTOPHER H	
			ART UNIT 1643	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/11/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/799,163	<b>Applicant(s)</b> HOLADAY ET AL.	
	<b>Examiner</b> Christopher H. Yaen	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-13 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3 and 5-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

**Re: Holaday *et al***

1. The amendment filed 12/18/2006 and 1/16/2007 are acknowledged and entered into the record. Accordingly, claim 4 is canceled without prejudice or disclaimer, and claims 12-13 are newly added. Claims 1-2 are withdrawn from further consideration as being drawn to non-elected subject matter.
2. Claims 3, and 5-13 are pending and examined on the merits.

### ***Claim Rejections Maintained - 35 USC § 112, 1<sup>st</sup> paragraph***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 10-11 and now newly added claims 12-13 under 35 USC § 112, 1<sup>st</sup> paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues that the claim amendments overcome the instant rejection because the claim have been amended to only recite a reduction of hyperproliferative disorders. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Although the claims have been limited to a composition capable of reducing hyperproliferative disorders, the claims still recite the term "vaccine" which carries with it an implied preventative capacity for the treatment of diseases such as cancer. As

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indicated in the previous office action mailed July 17, 2006, the current state of the art is extremely unpredictable with regards to "preventing" cancer and the instant specification has failed to provide one of skill in the art with adequate guidance for the use of a composition comprising SEQ. ID No: 10 in the prevention of cancer as encompassed by the claims.

Therefore, the rejection of claims under 35 USC § 112, 1<sup>st</sup> paragraph is maintained for the reasons of record.

***Claim Rejections Maintained - 35 USC § 102***

5. The rejection of claims 3,5-11, and now to newly added claims 12-13 under 35 USC § 102(b) as being anticipated by Holaday *et al* (WO 00/53219) is maintained for the reasons of record. Applicant argues that the instant application and the cited prior art reference share a common inventor and have further set forth that there was an unintentional delay in filing a priority claim. Applicants have indicated that a petition has been filed to accept an unintentional delay in claiming priority. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Upon review of the petition decision mailed 3/19/2007, the Office of Petitions has DISMISSED the petition for acceptance of a claim for late priority under 37 CFR §§1.78(a)(3) and 1.78(a)(6). (see petition decision mailed 3/19/2007). Applicant has failed to provide any further rebuttal to the prime facie case of anticipation set forth in

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the office action mailed July 17, 2006. Therefore, the rejection of claims under 35 USC 102(b) as being anticipated is maintained for the reasons of record.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CHRISTOPHER H. YAEN  
PRIMARY EXAMINER

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March 26, 2007